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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/596,479

06/19/2000

Jean-Christophe Audonnet

454313-2200.1

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20999

7590

10/10/2002

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EXAMINER

MOSHER, MARY

ART UNIT

PAPER NUMBER

1648

DATE MAILED: 10/10/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/596,479

Applicant(s)
Audonnet et al

Examiner
Mosher

Art Unit
1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/22/02.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-49 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☒ Certified copies of the priority documents have been received in Application No. 09/213,053.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☒ Other: Sequence alignment

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DETAILED ACTION

Double Patenting

Claim 37 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 2 of prior U.S. Patent No. 6,159,477. This is a double patenting rejection.

Claims 17-36, 38-49 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2, 10, 13-20, 24-31 of U.S. Patent No. 6,159,477. Although the conflicting claims are not identical, they are not patentably distinct from each other because the application claims encompass the previously patented subject matter.

Claim Rejections - 35 USC § 112

Claims 18 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims recite "the large subunit and small subunit site." Subunit of what?

Claim Rejections - 35 USC § 103

Claims 17-32, 38-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haanes et al 5,753,235 or 5,804,197 in view of Paoletti et al 5,843,456. Haanes discloses in great detail the construction and formation of canine herpesvirus (CHV) as an expression vector to be utilized in a vaccine delivery system in animals wherein a heterologous antigen or antigens or immunomodulatory substance may be inserted in various well defined non-essential regions of the CHV to be utilized as a vaccine delivery system, and claims the resulting viruses and body-treating compositions comprising the viruses (see especially claims 12-16, 48-57 of '235 and

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claims 16-51 of '197). Haanes specifically discloses recombinants designed to target distemper virus, rabies virus, parvovirus, parainfluenza virus, and *Borrelia burgdorferi*, see for example column 15 of '235 and column 16 of '197. Haanes also teaches insertion regions including the TK gene site, the CUL41-CUL38 region corresponding to the naturally deleted large and small ribonucleotide reductase subunit coding region, and the gC coding region (applicant's SEQ ID NO:5 is identical to canine herpesvirus gC, see attached sequence alignment as evidence). Haanes also teaches insertion of immunomodulatory polypeptides, use of effective promoters such as a CMV IE promoter, and administration by oral and nasal (mucosal) routes. Haanes differs from the claims in that Haanes does not specify which gene of the target organism to use in the recombinant vector vaccine. However, Paoletti et al teaches use of the HA or F gene of canine distemper virus, G gene of rabies virus, and the VP2 gene of canine parvovirus, in an analogous viral vector vaccine. See for example column 1, lines 20-45; Examples 7 and 12 for rabies G; Example 17 for canine parvovirus VP2; Example 19 for canine distemper HA and F. Haanes does not teach specific doses in CCID50 units as recited in claims 46-48, or the specific organization of inserts as recited in claims 23-25 and 28; however, it would have been within the ordinary skill of the art to perform routine optimization for dosage amounts, and to use any conventional arrangement of elements in expression cassettes, with reasonable expectation of success. The invention as a whole is therefore prima facie obvious, absent unexpected results.

Claims 17-28, 33, 34, 38-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haanes et al 5,753,235 or 5,804,197 in view of Cates et al WO 97/11093. The teachings of

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Haanes are discussed above. Haanes suggests recombinant CHV with heterologous parainfluenza DNA. Haanes differs from these claims in that the patents do not specifically discuss the hemagglutinin or fusion gene. However, Cates teaches that the hemagglutinin-neuraminidase and fusion proteins of parainfluenzaviruses are highly immunogenic and protective. Therefore it would have been obvious to choose either of these genes from canine parainfluenza virus to carry out the suggestions for a recombinant viral vector made in Haanes. The invention as a whole is seen as prima facie obvious, absent unexpected results.

Claims 17-28, 35, 36, 39-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haanes et al 5,753,235 or 5,804,197 in view of Barbour et al 5,777,095. The teachings of Haanes are discussed above. Haanes suggests recombinant CHV with heterologous B. burgdorferi DNA. Haanes differs from claims 35 and 36 in that the patents do not specifically discuss the OspA or ospB genes. However, Barbour suggest OspA and OspB as vaccine antigens for B. burgdorferi, therefore it would have been obvious to choose either of these genes to carry out the suggestions made in Haanes. The invention as a whole is seen as prima facie obvious, absent unexpected results.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary E. Mosher, Ph.D. whose telephone number is (703) 308-2926. The examiner can normally be reached on Monday -Thursday and alternate Fridays from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027. The fax phone number for this Group is now (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October 9, 2002


MARY E. MOSHER
PRIMARY EXAMINER
GROUP 1600 1600